DUMME58.001APC

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 035005	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU2003/000400**	International Filing Date *(day/month/year)* 3 April 2003	Priority Date *(day/month/year)* 3 April 2002

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61B 17/00, A61F 2/26

Applicant

MOORE, Colin Campbell Marshall

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☒ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of the report
3 November 2003	13 July 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer VINCE BAGUSAUSKAS Telephone No. (02) 6283 2110

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/000400

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 3, 9, 10, 13 at least are directed to a method of widening a penis. It is considered that the use of a dermal graft sutured to the exposed Bucks fascia and then reducing the penile skin comprises a first "special technical feature".

2. Claims 4 to 8, 12 at least are directed to a method of lengthening the penis. It is considered that dividing the suspensory ligament against the body of the symphysis pubis down to the inferior pubic arch and along the inferior surface of both the right and left conjoined inferior pubic rami comprises a second "special technical feature".

3. Claims 15 to 20, 27 at least are directed to a method of enhancement phalloplasty. It is considered that freeing the dorsal neurovascular bundle and separating the corpus spogiosum from the inferior surface of both said first and said second corpus cavernosum comprises a third "special technical feature."

4. Claims 28 to 33 are directed to a method of penile enlargement. It is considered that the post operative treatment regime following penile enlargement, whether exercise, drug or other, comprises a fourth "special technical feature".

The feature common to all of the claims is the use of a post operative treatment regime. However this common feature is generic in the art: see for example a partially completed search has found the following Internet documents;

http://www.altermd.com/penhancement/girth.htm published 5 May 1998
http://www.psurg.com/PL4QA.htm published 30 January 1997
http://www.psurg.com/humber99.html published 3 March 2001

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-8, 11, 14, 26	YES
	Claims	1-3, 9, 10, 12, 13, 15-25, 27-35	NO
Inventive step (IS)	Claims	4-8, 11, 14, 26	YES
	Claims	1-3, 9, 10, 12, 13, 15-25, 27-35	NO
Industrial applicability (IA)	Claims	1-35	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The relevant citations as discovered in the ISR are:

D1) ALTER G. "Girth Enlargement"

D2) "Penis Lengthening Surgery – Questions and Answers"

D3) JAMES D. "The Perfect Penis in about an Hour"

D4) AU 53864/98 (742359) B (MOORE)

D5) ALTER G.J. "Penile Enlargement Surgery"

D6) ALTER G.J. "Augmentation Phalloplasty"

D7) LUE T.F. and EL-SAKKA A.I. "Lengthening Shortened Penis Caused by Peyronie's Disease Using Circular Venous Grafting and Daily Stretching with a Vacuum Erection Device"

D8) AUSTONI E. and GUARNERI A. and CAZZANIGA A. "A New Technique for Augmentation Phalloplasty: Albugineal Surgery with Bilateral Saphenous Graft –Three Years of Experience"

D9) AUSTONI E. and GUARNERI A. and GATTI G. "Penile elongation and thickening – myth? Is there a cosmetic or medical indication?"

D10) SHIRONG L. And XUAN Z. and ZHENGXIANG W. And DONGLI F. and JULONG W. and DONGYUN Y. "Modified Penis Lengthening Surgery: Review of 52 Cases"

D11) AU 79900/98 (760083) B (MOORE)

D12) RIGAUD G. and BERGER R.E. "Corrective Procedures for Penile Shortening due to Peyronies's Disease"

<u>NOVELTY (N) 1-3, 9, 10, 12, 13, 15-25, 27-35</u>

D2) discloses under the question "What is the follow-up after surgery?" that lead weights or other forms of traction are started a few weeks after the stiches are out. The purpose of which is to reduce retraction, stretch the shaft skin and in some cases results in further lengthening. Traction is a form of post-operative treatment and the aim as disclosed in the citation is to maintain the prior mentioned lengthening. Therefore the invention as defined in claims 28, 29 and 30 (as defined for "lengthening") is explicitly disclosed in the citation and for which novelty is lacking.
The invention as defined in claim 1 is not disclosed by D2) since the citation concerns itself with penis lengthening and not widening.

Continued

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
, X AU 79900/98 (760083) B (MOORE) (D11)	8 May 2003	12 August 1998	13 August 1997

D11) discloses all of the features of claims 15 to 25, 27 in this instance except for the feature of "said method further including the step of following a post-operative treatment regime". It is considered the PSA would apply post operative care including drug therapy as disclosed in D1) to ensure the survival of the graft and/or to reduce pain associated with the procedure as a normal part of such a procedure. Thus the invention as defined in claims 15 to 25, 27, must be obvious and thus lack an inventive step. It is also considered that the invention as defined in claims 28 to 30, 32 and 35, are also obvious and thus lack an inventive step.

With regard to the document(s) listed in Box VI under "certain documents cited", these are documents published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D3) discloses penile lengthening and the use of medications to prevent scar tissue and weights to increase the length of the penis. The weights is used post surgery. As disclosed in the citation, penile lengthening was first performed to treat microphallus or otherwise known in the art as buried penis condition. Therefore the invention as defined in claims 28, 29, 30 (as defined for "lengthening"), 31, 32 and 35 is explicitly disclosed as for which novelty is wanting.
The citation does not disclose the features of claim 1 in particular that the dermal fat graft is sutured to the exposed Bucks facia, merely that dermal strips are inserted on each side of the penile shaft.

D4) explicitly discloses the invention as defined claims 9, 10, 13 and 27 in this instance. See D4)'s claims.

D5) discloses at page 73, col 1, under "Girth Increase" to page 75, col 2, that the penis is "partially de-gloved" and "dermis-fat" graft, harvested from "vertical medial buttocks" is placed about the Buck's Fascia (see Fig 3) and stay sutures of "Vicryl" are used to secure the graft to "lateral penopubic region" and that the lateral edges are sutured to the Buck's fascia. Skin is the replaced over the graft. Therefore the invention as defined in claim 1 to 3, 9, 10, 13 and 27 is explicitly disclosed by the citation.
The citation also discloses postoperative treatments at page 74, col 1 of a dressing to allow graft "take" and page 75, col 2 the use of weights to reduce shrinkage. Therefore the invention as defined in claims 28 to 30 is explicitly disclosed.
The citation teaches away from the invention as defined in claims 11, 14, 21 and 26 in this instance as disclosed in the second paragraph at col 1, page 73.

D6) is by the same author as D50 and is similar in disclosure. From page 894 under "Girth" to page 896 penile widening by sutured dermal-fat graft is disclosed. The invention as defined in claims 1 to 3, 9, 10, 13, 27 to 30 in this instance is considered to be not novel.
D6) at page 889 discloses buried penis condition. It is considered that the penile lengthening procedures as disclosed are used to treat said buried penis condition. Therefore claim 31 is considered to be not novel in the light of said citation.

D7) disclose a penile lengthening technique at page 1141 under "Surgical technique" to the end of paragraph 1, col 1, page 1142 followed by a postoperative treatment regime at the end of paragraph 2, col 1, page 1142 of using a vacuum device. It is considered that the surgical technique as disclosed is equivalent to the surgical procedure of claim 15 in this instance. Combined with the disclosed postoperative treatment, it is considered that claim 15 in this instance is not novel.
It is also considered that claims 12 and 27 is not novel for the reasons given above.
Since D7) discloses a vacuum device postoperative treatment, it is considered that claims 28 to 30, 33 and 34 is not novel.

D8) discloses at page 247, col 1 the use of antibiotic association; the use of corticosteroids at page 249, col 1; video sex stimulation at page 249, col 1 delivered post penile enlargement surgery. Therefore it is considered that claims 28 to 30, 32 to 35 are not novel.
Note: this is a category "P" document. It is considered that the Accepted date listed as 22 May 2002 is equivalent to a filing date of a patent document. No form publication date has been established and would be left to each jurisdiction to determine from their own library holdings.

D9) discloses at page 50, col 1 the use of video sex stimulation gymnastics and corticosteriod use delivered post penile surgery. Therefore it is considered that claims 28 to 30, 32 to 35 are not novel.

D10) discloses at page 599 under "Postoperative Management" the use of drugs to prevent nocturnal erections that are harmful to the wound healing process following penis lengthening surgery. The use of the drugs is considered to help "maintain the outcome of the enlargement" as defined in claim 28 in this instance. Therefore it is considered that claims 28 to 30, 32 and 35 are not novel.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D11) Refer to Box VI

D12) does not on balance disclose the invention as defined in claim 15.

INVENTIVE STEP (IS) 1-3, 9, 10, 12, 13, 15-25, 27-35

Claims 1-3, 9, 10, 12, 13, 15-25, 27-35 as above

D1) discloses that dermal-fat is obtained either from the buttock creases or inside buttock cheeks of a patient. The penis is circumcision incised and dermal-fat is grafted onto Buck's facia (see Figure 1). The skin is replaced over the graft. Post operative care is performed on the now thickened penis.
What is not explicitly disclosed as define in claim 1 is that the penis is degloved. However it is considered that the person skilled in ıe art (PSA) would understand the aforementioned circumcision incision to mean degloving to expose the Buck's facia.
Furthermore it is not explicitly disclosed that the dermal fat is sutured to the exposed Buck's facia. However suturing of the graft would fall into normal operative techniques. Thus it is considered that the invention as defined in claims 1 to 3 lacks an inventive step since the steps contained in claim 1 would fall under normal and obvious surgical procedures.
It is considered that post operative care as disclosed in D1) includes drug therapy to ensure the survival of the graft and/or to reduce pain associated with the procedure. The PSA would apply such post operative regimes as a normal part of such a procedure. Thus the invention as defined in claims 28 to 30 (as defined for "widening"), 32 and 35, must be obvious and thus lack an inventive step.

D2) does not disclose that the penis lengthening procedure is for the purpose to treat buried penis condition. However it is commonly known in the art that penis lengthening is performed on men suffering said condition. Post operative treatment regimes as defined in claims 28 and 29 would be an obvious step that the PSA would have the persons with buried penis undergo post penis lengthening surgery. Therefore the invention as defined in claim 31 lacks an inventive step.
The PSA would apply post operative drug regimes as a normal part of such a procedure. Thus the invention as defined in claims 32 and 35, must be obvious and thus lack an inventive step.

D4) discloses all of the features of claims 1 to 3 in this instant expect for the feature of a post operative treatment regime: see the claim . However, as discussed with relation to D1), D2) and D3) such treatment regimes, be they drugs to reduce pain and scarring, r the use of weights to prevent retraction, are a normal and obvious part of penile widening surgery. The application of the missing feature to the method of the claims of D4) would be an obvious step that the PSA would undertake and thus claims 1 to 3, 28 to 30, 32 and 35 in this instance lacks an inventive step.
D5) does not disclose that the "Penile Lengthening" procedures taught from page 71, col 1 onwards, is used to treat for buried penis condition, but it would be obvious to the PSA that the procedure can be used as such. Therefore the invention as disclosed in claim 31 in this instance is considered to be obvious and lack an inventive step.

D5) and D6) do not explicitly disclose the features of claims 32 and 35 in this instance. Drug treatment regimes following surgery are considered to be a normal and obvious step that the PSA would do and thus claims 32 and 35 are considered to lack an inventive step.

D9) and D10) do not disclose that the penis lengthening surgery is used to treat for buried penis condition, but it would be obvious to the PSA that the procedure can be used as such. Therefore the invention as disclosed in claim 31 in this instance is considered to be obvious and lack an inventive step.